CE 0088

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ACCU-CHEK®
Integra

BLOOD GLUCOSE MONITORING SYSTEM

Complete Instructions for Use

Roche

On packaging, on the type plate of the meter, on the lancing device itself and in these instructions for use you may encounter the following symbols, shown here with their meaning:

Please consult instructions for use

REF Catalogue number

IVD For in vitro diagnostic use

Store at

Use by/Expiry date

LOT Lot number

CE 0088 Blood glucose meter and test strips: These products fulfil the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

Lancing device and lancets: These products fulfil the requirements of Directive 93/42/EEC on medical devices.

CE AST cap: This product fulfils the requirements of Directive 93/42/EEC on medical devices.

Manufacturer

Caution (refer to accompanying documents). Please refer to the safety-related notes in the manual accompanying this instrument.

For single use only

STERILE R Sterilized using irradiation

Last update user information: November 2004

This booklet consists of four parts.

Part 1
Instructions for use (User's Manual) for the Accu-Chek Integra blood glucose meter.

Part 2
Instructions for use for the Accu-Chek Softclix lancing device.

Part 3
Instructions for use for the Accu-Chek Softclix AST cap, used to collect blood from alternative sites (accessory for the Accu-Chek Softclix lancing device).

Part 4
Appendix

Please read the instructions in this booklet carefully and completely before performing the first measurement. Should you have any questions, call the Accu-Chek Enquiry Line on 1800 251 816.

Please read with special attention all text in this booklet that is preceded by the following symbols:

This symbol signifies a possible risk of injury or of damage to your health.

This symbol indicates that your meter or lancing device is at risk of being damaged.

This symbol highlights important information.

The Accu-Chek Integra meter is intended for use by one person only.

Use of the same Accu-Chek Integra meter by more than one person or for performing blood glucose measurements in more than one person poses an infection risk.

Any object coming into contact with human blood is a potential source of infection (see: National Committee for Clinical Laboratory Standards: Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue. Approved Guideline, NCCLS document M29-A, 1997).

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Part 1

ACCU-CHEK® Integra

BLOOD GLUCOSE METER

User's Manual

1.1 Your blood glucose meter at a glance

① SET button
Press this button to enter the Set menu and change the settings.

② Display window

③ ON/OFF button
Press this button **only** if you want to test your blood glucose or to turn the meter off.

④ Drum compartment release button

⑤ Drum compartment

⑥ Test strip drum

⑦ Test strip

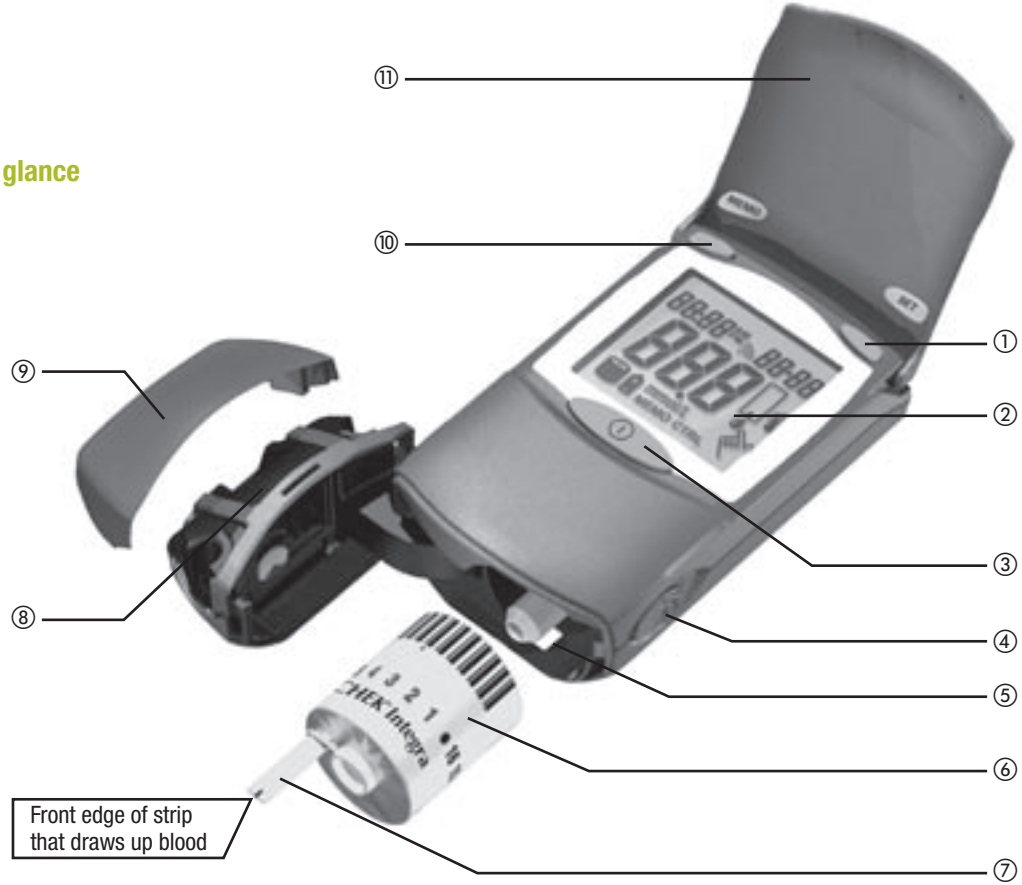
⑧ Optical system

⑨ Optical system cover*

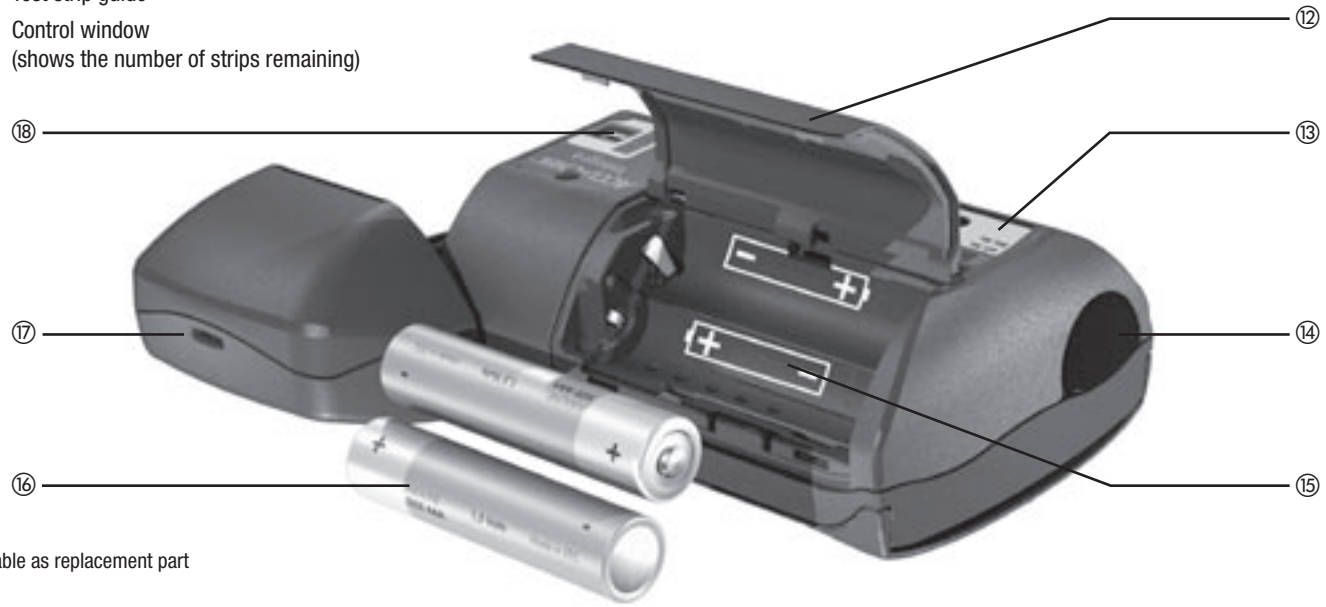
⑩ MEMO button
Press this button to view results stored in the meter's memory.

⑪ Display cover*

* available as replacement part



⑫ Battery compartment cover*
⑬ Type plate
⑭ Infrared window
⑮ Battery compartment
⑯ Batteries: Type AAA, LR 03, AM 4, Micro
⑰ Test strip guide
⑱ Control window
(shows the number of strips remaining)



* available as replacement part

1.2 Main features

With your Accu-Chek Integra blood glucose meter you can test your blood glucose simply and with confidence.

Test strip drum instead of individual test strips
You never need to touch a test strip. Simply insert a drum with 17 test strips into the Accu-Chek Integra meter.

Easy to operate
Turn on the meter, apply blood, read the result, press the button to eject the test strip.

Automatic coding
Every test strip drum has its own bar code. The Accu-Chek Integra blood glucose meter is automatically coded when you insert a new drum, a process which provides the meter with information on the specific characteristics of the test strips.

Reliability
The Accu-Chek Integra blood glucose meter checks each test strip. If it finds a defective strip, it lets you know before you apply blood.

Blood volume checking
The Accu-Chek Integra blood glucose meter can tell when you have applied sufficient blood (approximately 1.5 µL (1 microlitre = 1 thousandth of a millilitre). It waits until then before starting the measurement. If the measurement does not start, you may apply more blood.

Easier way of dosing blood
Blood is drawn up into the test strip through capillary action. This means that the collection of blood from alternative sites, such as the forearm, the upper arm or the base of the thumb, is much easier.

Downloading data to a PC
The Accu-Chek Integra blood glucose meter has an infrared interface which enables you to download results to a PC running suitable software.

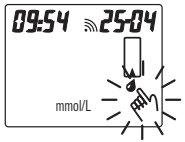
We recommend that you use an Accu-Chek Softclix lancing device to obtain capillary blood samples (see Part 2 of this booklet).

1.3 About this manual

This manual will help you get to know your new Accu-Chek Integra meter step by step. It will provide you with all the information you need to operate, troubleshoot, and care for your meter. It is important to remember that, in order to keep your meter in tip-top condition, you need to comply with all instructions given in addition to following the correct operating procedures. The Accu-Chek Integra meter is a precision instrument. Improper treatment can impair its function.

Throughout this manual you will see examples of what the display looks like. Elements that flash are shown surrounded by a halo.

Example:



You have turned on the meter to perform a blood glucose measurement. The display shows a number of elements, some of which (the blood drop and the hand symbol) are flashing.

The date, time and blood glucose results shown in the display are intended only as examples. They will not be the same as those shown by your Accu-Chek Integra meter. The blood glucose meter that is depicted displays blood glucose results in mmol/L (see Chapter 2.2 “Checking the blood glucose unit”) and has been set to 24-hour format (see Chapter 3.3 “Changing the time/date format”).

We recommend that you start by familiarizing yourself with all of the elements of your Accu-Chek Integra meter shown on pages 10 – 13 of these instructions. Practise all of the operations described in these instructions, and also practise testing. That way you will always have a dependable partner to accompany you through the day.

2 Initial steps before testing

2.1 Checking the contents

Check that your Accu-Chek Integra Blood Glucose Monitoring Kit is complete. The package contents are listed on the box.

If anything is missing, please contact customer support (see Chapter 19 for details).

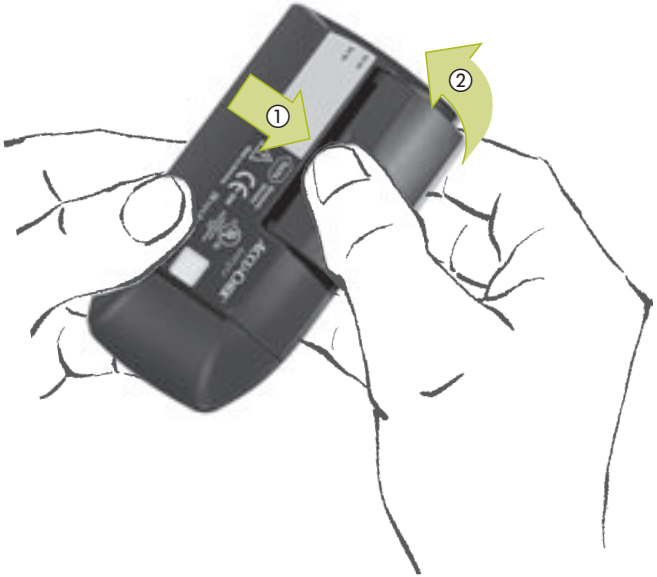
2.2 Checking that the correct unit is displayed

Blood glucose results can be displayed in two different units (mmol/L or mg/dL). Consequently, Roche sells two different versions of the same meter. Check that your meter displays the unit you are accustomed to. On the back of your meter you will find the unit for which your instrument is coded. Ask your doctor if you do not know which is the right unit for you. The setting cannot be changed.

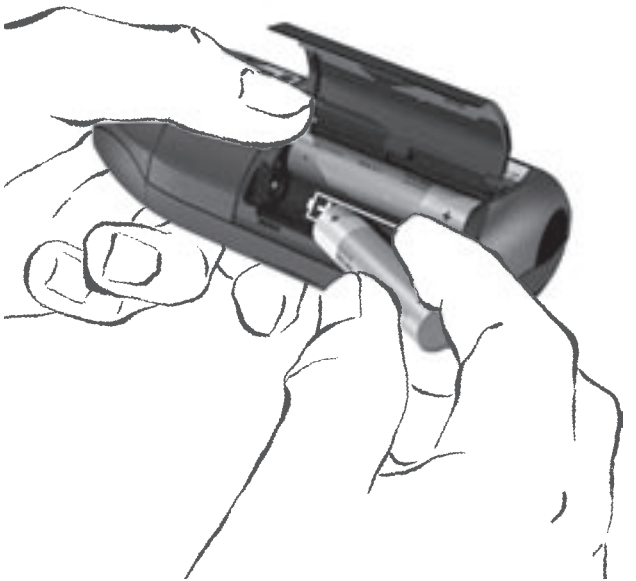
If the wrong unit is printed on the type plate, please consult the retail outlet where the meter was purchased. Using the wrong units can cause you to misinterpret the test result.

2.3 Inserting or replacing batteries

- If the meter is on, turn it off.
- Press lightly on the lid of the battery compartment and slide it in the direction of the arrow (1).
- Open the battery compartment (2).



- Remove any used batteries.
- Insert two batteries (type AAA, LR 03, AM 4 or Micro). Make sure that the minus (-) pole of the battery is next to the minus contact in the battery compartment.



2.3 Inserting or replacing batteries

- Fold the lid of the battery compartment down and slide it closed again.
  There will be an audible CLICK as it closes.

After you have inserted the batteries, the meter turns on and the motor inside runs for about 10 seconds.

A meter already containing a test strip drum then automatically turns off.

A meter that does not yet contain a test strip drum emits a beep and displays the following message for about 10 seconds:

This means that you have not yet inserted a test strip drum. The meter then automatically turns off.

A new set of batteries provides enough power to carry out a minimum of 500 blood glucose tests.

Do not use rechargeable batteries. They do not provide sufficient voltage and will only allow you to perform a few measurements before they need recharging.

When the battery symbol appears in the display for the first time, it indicates that the battery is running low. You can perform about a further 50 tests. We recommend, however, that you replace the batteries as soon as possible (see the following information). By then the battery will have been considerably drained, and changeable conditions (cold surroundings) can affect its performance even further.

To keep things simple, we recommend you use up the current drum of strips before replacing the batteries. Otherwise, it may take the meter a long time to advance the first test strip from the next drum, and the “use-by” date warning may also be lost (see Chapter 2.5 “Inserting or replacing the test strip drum”).

2.3 Inserting or replacing batteries

When you replace the batteries, your stored results are retained in memory. However, you will need to re-enter the time and date. If you fail to do so, any blood glucose test results you obtain from this point forward will be displayed and saved without time and date. In this case, the test results saved in memory will be numbered consecutively so you can still see the order in which you took the readings.

Never throw batteries into a fire. This is dangerous because they may explode.

Remove the batteries if your Accu-Chek Integra meter is to remain unused for some time.

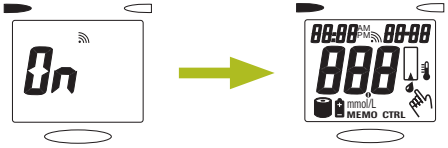
Think of the environment. Dispose of used batteries sensibly.

2.4 Performing a full display test

To check that all of the display elements are functioning correctly, you should carry out a full display test.

- If the meter is on, turn it off.
- Press and hold down the MEMO button.

The meter turns on. “On” appears briefly in the display. While you hold down the MEMO button, all of the display elements are visible. Compare the display screen of your meter with the one shown below.



MEMO button | Full display test

If any of the display elements are missing or the unit shown for the blood glucose results is not the correct one, please contact Customer Support (see Chapter 19 for details) to exchange the meter.

2.4 Performing a full display test

- Release the MEMO button.

  The standard display test screen that is shown each time the meter is turned on appears briefly. When it disappears, the meter is in memory. If no results have yet been saved, three bars are displayed.

Standard display test | No results in memory

You can perform a full display test whenever you wish. If there are already results saved in memory, when you release the MEMO button the most recently saved result is displayed.

- Press the ON/OFF button to turn the meter off.

The meter automatically turns off if you keep the MEMO button pressed for more than 90 seconds.

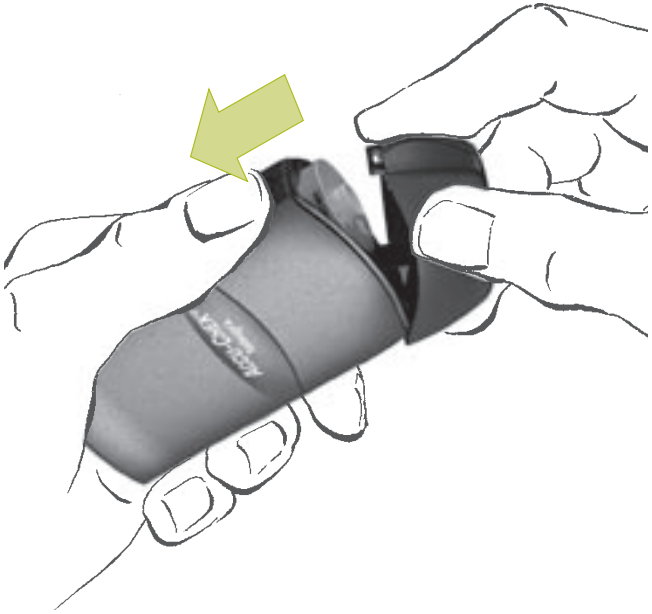
2.5 Inserting or replacing the test strip drum

- Read the package insert that came with the test strip drums.
- If the meter is on, turn it off.
- Wait for the motor to stop before you open the meter.

Only open the meter when it is turned off and the motor is not running. Opening the drum compartment when the meter is turned on may result in damage to the meter.

2.5 Inserting or replacing the test strip drum

- Slide the release button on the right side of the meter in the direction indicated by the arrow. The drum compartment opens.



- To exchange the drum, first tip the meter upright. The old drum drops out.

You can dispose of used drums with your regular household waste.

2.5 Inserting or replacing the test strip drum

- Insert the new test strip drum.
- Close the drum compartment.
  The meter automatically moves the drum to the correct position and reads the code on the drum.

A dot appears in the small control window on the reverse side of the meter. This dot indicates that you have just inserted a drum. When you perform a blood glucose test, the meter counts the number of test strips that have been used and displays the number of strips remaining.

Use only test strips that are within the expiry date. Expired test strips can produce incorrect results. Incorrect results can cause the wrong therapeutic decision to be taken and so produce adverse health effects. The expiry date is printed next to the ⌛ symbol on the container.

2.5 Inserting or replacing the test strip drum

Use only new test strip drums on which the aluminium foil (the “silver ends”) is intact on both sides. Your blood glucose test results may be incorrect if damaged drums are used in the meter. Incorrect results can cause the wrong therapeutic decision to be taken and so produce adverse health effects.

Handle the test strip drums with extreme care! Only remove a test strip drum from its container when you intend to use it. The container protects the aluminium foil on the drum from damage.

When performing a quality control test, you need the list of expected values given on the peel-off label attached to the test strip drum container (see Chapter 6 “Checking the Accu-Chek Integra meter”). You may, for instance, wish to stick the peel-off label in your notebook or diary. When conducting quality controls always check that the peel-off label with the concentration table belongs to the test strips that are currently in the meter.

Use only Accu-Chek Integra test strip drums. Other test strips cannot be used to perform measurements.

If you insert a different test strip drum, the following message will be displayed:

When all the strips have been used, the dot reappears in the control window.

▶ Insert a new test strip drum.

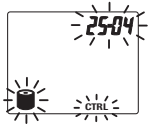
If you do not insert a new test strip drum, the following message will be displayed the next time you turn on the meter:

“End” and the drum symbol flash in the display, indicating that the drum is empty.

2.5 Inserting or replacing the test strip drum

When you insert a new drum the number of days the drum has been in the meter is counted automatically. Each drum must be used up within a 90-day use-by period.

After 90 days the date, the drum symbol and “CTRL” flash in the display.



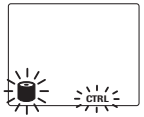
The drum has been in the meter for 90 days. You are asked to perform a quality control test in order to check the test strips. Carry out a quality control check (see Chapter 6 “Checking the Accu-Chek Integra meter”). If the measurement produces the correct results, you may continue to use the test strips. If the results are incorrect, you need to insert a new drum.
Following the quality control check, “CTRL” disappears from the display. The drum symbol and the date continue to flash in order to draw attention to the fact that the drum has been in use for more than 90 days.

The meter is unable to calculate the 90-day use-by period if you

- remove a partly used drum from the meter and then insert it again,
- change the batteries and leave a partly used drum in the meter.

The meter has no way of telling when the drum was first inserted or how long the partly used drum has already been in the meter.

The drum symbol and “CTRL” flash in the display.



You are asked to perform a quality control test in order to check the test strips. Carry out a quality control check (see Chapter 6 “Checking the Accu-Chek Integra meter”). If the measurement produces the correct results, you may continue to use the test strips. If the results are incorrect, you need to insert a new drum. Following the quality control check, “CTRL” disappears from the display. The drum symbol continues to flash in order to draw attention to the fact that the meter cannot calculate the use-by period.

If you insert a partly used drum in the meter, a dot appears in the control window on its reverse side. When you then next turn on the meter, it rotates the drum until it finds the first chamber containing a test strip. The lower the number of test strips in the drum, the longer the process takes. The control window allows you to see the drum being rotated from one chamber to the next.

3 Basic settings

You may now move to the SET menu to turn the beep tone on or off, to set the year, time and date, and to define the time and date format.

When you turn on your Accu-Chek Integra meter for the first time, it has the following settings (which you can change):

- Beep tone: on
- Year: 2000
- Display format for the time and the date:
  24 h (with the accompanying date format day-month/DD-MM)
- Time: 00:00
- Date: 0-0

If you do not set the time and date, a series of zeros will be displayed in place of time and date when you take a reading.
In that case, statistical evaluations (in the electronic notebook, see Chapter 5 “Using the Accu-Chek Integra meter as an electronic notebook”) cannot be performed as they can only use data stored together with the time and date. To distinguish readings internally (in memory), they are numbered consecutively.

The procedure for changing the settings is as follows:

- Press the SET button to call up the SET menu.
  The field currently flashing in the menu may now be changed.
- Press the MEMO button to change the current setting.

  Numerals such as the year, time and date can be incremented to a certain value, then the count-up starts again from the beginning.

  In the case of settings where you have two options, e.g. the beep tone setting and the time/date format, pressing the MEMO button presents each option in turn.
- Press the SET button to save the chosen setting and move on to the next setting.
- You can change any setting you wish. Press the SET button repeatedly until the setting you wish to change is displayed flashing. A test strip is not advanced.
- You can close the set menu at any time by pressing the ON/OFF button. All settings you have entered are saved and the meter turns off.

Only turn on the meter with the SET button when you intend to change the settings.
If you turn on the meter with the ON/OFF button and there is a drum in the meter, a test strip will be advanced.

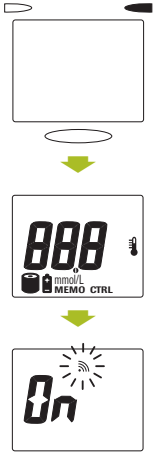
3.1 Turning the beep tone on or off

With the beep tone turned on, the meter beeps

- when it asks you to apply blood or control solution,
- when it starts to test, as confirmation that the test strip has received a sufficient amount of blood or control solution,
- when the result is displayed
- each time it displays a message.

▶ Check the meter is off.

▶ Press the SET button.
The meter turns on without advancing a test strip from the drum.



The symbol for the beep tone flashes in the display window, and “ON” appears.

▶ Press the MEMO button to turn off the beep tone. “OFF” appears in the display.

If you press the MEMO button again, “ON” reappears.

If you wish to set the year, leave the meter turned on and proceed to the next section, 3.2.

If not, press the ON/OFF button to turn the meter off. The current settings will be saved automatically.

3.2 Setting the year

If you have a new meter or you have just replaced the batteries, the date will be set to 00.00.2000, and the time to 00:00 hours (24-hour format) or 12:00 a.m. (12-hour format). The correct time and date are needed to enable you to unambiguously identify your blood glucose test results, perform statistical analysis and to transfer them from your meter's memory to a computer (see Chapter 5.4 "Downloading data to a PC or handheld computer").

- Check the meter is off.
- Press the SET button.
  The meter turns on without advancing a test strip from the drum.
- Press the SET button repeatedly until the year setting flashes at top right of the display. The default value is 2000.

- Press the MEMO button repeatedly to set the year. The meter scrolls upwards through the year values.

If you hold the MEMO button down, the meter fast-scrolls forward to 2032 and then begins again at 2000.

If you wish to define the time and date format, leave the meter turned on and proceed to the next section, 3.3.

If not, press the ON/OFF button to turn the meter off. The current settings will be saved automatically.

The year is not displayed during testing or review of blood glucose test results. It is still important, however, as February 29 in a leap year will only be recognized if the year is properly set. The current year setting is also needed to unambiguously identify your blood glucose test results if you transfer them from your meter's memory to a computer (see Chapter 5.4 "Downloading data to a PC or handheld computer").

3.3 Changing the time/date format

You can choose between the 24-hour format (0:00 to 23:59), in which case the date format is DD-MM (day followed by month), and the 12-hour format (1 to 12 o'clock with a.m. or p.m.). In the latter case the date format changes to MM-DD (month followed by day).

- Check the meter is off.
- Press the SET button.
  The meter turns on without advancing a test strip from the drum.
- Press the SET button repeatedly until "24h" is displayed. 24-hour format is selected.
  The time is set to 00:00.

- Press the MEMO button to select 12-hour format.
  In the display you see "12h" and the time is set to 12:00 a.m.

If you press the MEMO button again, "24 h" reappears.

If you wish to set the time, leave the meter turned on and proceed to the next section, 3.4.

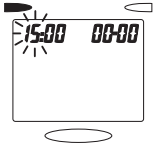
If not, press the ON/OFF button to turn the meter off. The current settings will be saved automatically.

If you do not set the time and date, these fields will be filled with zeros during testing. Your blood glucose test results saved in memory will be numbered consecutively. However, only test results that are saved with the time and date will be included in the statistics (see Chapter 5 "Using the Accu-Chek Integra meter as an electronic notebook").

3.4 Setting the time

- Check the meter is off.
- Press the SET button.
  The meter turns on without advancing a test strip from the drum.
- Press the SET button repeatedly until the **hour** field flashes.

- Press the MEMO button repeatedly to set the hour.

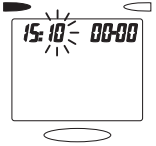


24-hour format: If you hold the MEMO button down, the meter fast-scrolls forward to 23 and then begins again at 0.

12-hour format: If you hold the MEMO button down, the meter fast-scrolls forward to 12 p.m. and then to 12 a.m.

- Press the SET button again.
  The **minute** field flashes.

- Press the MEMO button repeatedly to set the minute.



If you hold the MEMO button down, the meter fast-scrolls forward to 59 and then begins again at 0.

If you wish to set the date, leave the meter turned on and proceed to the next section, 3.5.

If not, press the ON/OFF button to turn the meter off. The current settings will be saved automatically.

At temperatures below –10°C the batteries do not have enough power to keep the internal clock functioning. In this event the clock must be reset.

3.5 Setting the date

- Check the meter is off.
- Press the SET button.
  The meter turns on without advancing a test strip from the drum.
- Press the SET button repeatedly until the **month** field flashes.
  24-hour format: DD-MM
  12-hour format: MM-DD

- Press the MEMO button repeatedly to select the correct month.

If you hold the MEMO button down, the meter fast-scrolls forward to 12 and then begins again at 1.

- Press the SET button again. The **day** field flashes.
  24-hour format: DD-MM
  12-hour format: MM-DD

- Press the MEMO button repeatedly to select the correct day.

If you hold the MEMO button down, the meter fast-scrolls forward to 31 and then begins again at 1.

- Press the ON/OFF button to turn the meter off.
  The current settings will be saved automatically.

4 Testing blood glucose

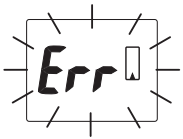
The Accu-Chek Integra meter is intended for use by one person only.

Use of the same Accu-Chek Integra meter by more than one person or for performing blood glucose measurements in more than one person poses an infection risk.

Any object coming into contact with human blood is a potential source of infection (see: National Committee for Clinical Laboratory Standards: Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue. Approved Guideline, NCCLS document M29-A, 1997).

Keep the test strip away from skin unless you are touching it against blood. Residues (e.g. of skin cream, food or drink) on the skin can find their way onto the strip and may produce incorrect results. Incorrect results can cause the wrong therapeutic decision to be taken and so produce adverse health effects.

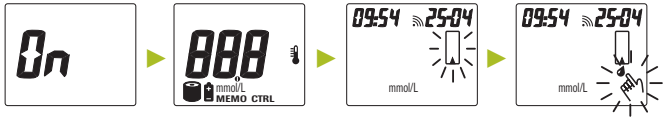
Do not bend the test strip, or the following error message will be displayed.



The meter turns off automatically after 5 minutes of non-use.

- Wash your hands thoroughly with warm water and soap and dry them well.
- Open the display cover.
- Press the ON/OFF button. The meter turns on.

The following messages appear in turn on the display.



Standard display test | A test strip is being advanced | You may now apply blood

The standard display test takes about 2 seconds.

- Check that all the segments making up the numerals are properly displayed.

If a segment is missing, test results may be displayed inaccurately (e.g. through a "3" being confused with a "3"). If this happens, call your local customer support and service centre.

- Use the Accu-Chek Softclix lancing device to prick the side of a fingertip. Gently squeeze the fingertip to develop a small drop of blood (please turn to Part 2 and read the instructions for using the Accu-Chek Softclix lancing device).

For testing with blood collected from alternative sites, such as the forearm, or the base of the thumb, please turn to Part 3 and read the instructions for using the Accu-Chek Softclix AST Accessory.

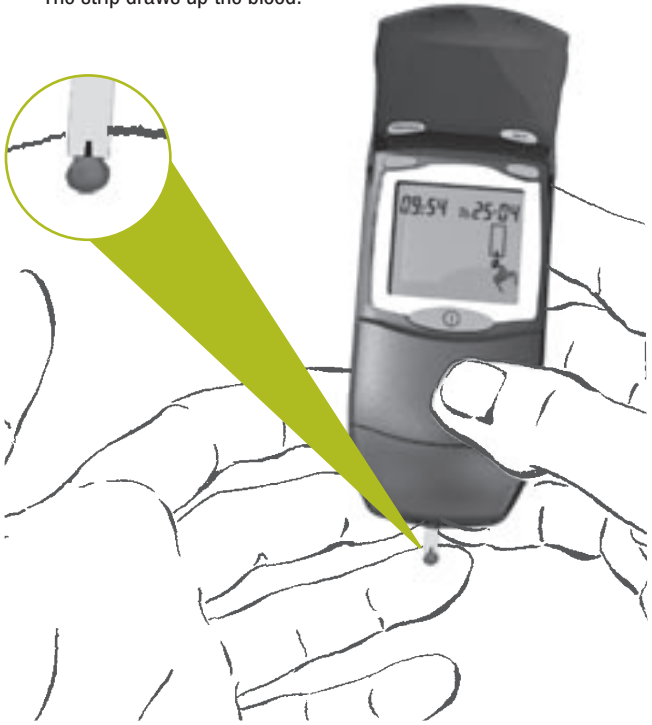
- **Wait until the flashing hand and blood drop symbol appear** in the display and the meter beeps (provided the beep tone is turned on).

You now have approximately 5 minutes in which to apply blood. After this time the meter automatically turns off. This strip can no longer be used. If this occurs, press the ON/OFF button to eject the test strip. Start the blood glucose measurement again with a new test strip.

- Hold the meter so **the test strip is pointing downwards** at a slight angle (see illustration).

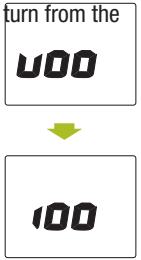
Always hold the meter so the test strip is pointing downwards when you are applying blood. If you hold it with the test strip pointing upwards, blood may enter the meter and contaminate it.

- Touch the blood drop against the front edge of the test strip near the black notch without delay.
  The strip draws up the blood.



As soon as a sufficient amount of blood has been drawn up, the meter beeps and the test commences automatically. 000 appears in the display at the start of the test.
If the test does not commence, you did not apply sufficient blood. You can then apply more blood (see the package insert that came with the test strip drum).

As measurement progresses, the three 000 disappear in turn from the display.

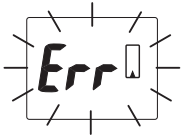


On completion of the test, the result appears in the display together with the flashing test strip symbol. The meter will save the result simultaneously.

- Hold the meter upright over a waste bin.
- Press the ON/OFF button.
  The meter turns off and the used test strip falls out.

If you do not turn off the meter, it turns off automatically after about 60 seconds. The test strip then remains in the meter. When you turn on a meter still containing a used test strip, this is merely ejected and the meter automatically turns off again.

Always let the meter eject the test strip.
Never pull the test strip from the meter while the test is running.
Measurement is then interrupted and the following message is displayed:



Once a test strip has been ejected, never push it back into the test strip chamber. This could damage the meter.
If a test strip is pushed back into the test strip chamber, the following message is displayed when the meter is turned on:

The meter does not allow a test to be performed.

Please dispose of used test strips with your regular household waste.

4.1 Plausible results

Your Accu-Chek Integra meter measures blood glucose within a defined range (0.6-33.3 mmol/L).

Values below this range are displayed as:

Your blood glucose result is below 0.6 mmol/L.

Values above this range are displayed as:

Your blood glucose result is above 33.3 mmol/L.

These values are not used for statistical calculations (see Chapter 5.3 “Highest value, lowest value, average”).

If the test result agrees with the way you feel, follow your doctor’s advice. If the way you feel does not agree with this test result, please perform a quality control check with the Accu-Chek Integra Control solution and a new test strip. Repeat the blood glucose test. If you feel the new result is also implausible please consult your doctor.

4.2 Implausible results

If your meter repeatedly displays error messages, or if you have reason to doubt the validity of a test result, please check the following points.

- Did you perform the test as directed (see Chapter 4 “Testing blood glucose”)?
- Did you wait for the flashing hand symbol and blood drop symbol to appear before applying blood?
- Did you wash your hands with warm water and soap to improve the blood flow and to remove any residues, e.g. of food, drink or skin cream? Did you dry your hands well?
- Did you just gently squeeze your fingertip to develop the drop of blood?
- Did you apply blood to the test strip without delay after the blood drop was formed?
- Did you perform the test within the correct temperature range (+10 °C to +40 °C)?
- Did you use a test strip drum whose 90-day “use-by” period has not expired (see Chapter 2.5 “Inserting or replacing the test strip drum”)?
- Did you observe the proper storage conditions for the meter and test strip drum (see Chapter 8 “Measurement and storage conditions” and the package insert that came with the test strip drum)?

If you have checked these points and still receive error messages or doubt the validity of results, please contact Customer Support (see Chapter 19 for details).

5 Using the Accu-Chek Integra meter as an electronic notebook

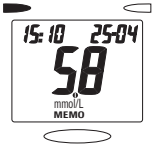
5.1 Memory

Your Accu-Chek Integra meter has a 100-value memory for saving results together with time and date (provided the latter are correctly set). You do not need to save a result specially, the meter does it all for you. Once all the memory locations are full, the meter automatically overwrites the oldest entry. All results in memory are consecutively numbered from 1 (most recent) to a maximum of 100 (oldest).

In addition to results, your meter also stores all relevant additional information and display messages. For example, results flagged as control results (see Chapter 6.2 “Performing a quality control check”) are always displayed together with “CTRL”. Results obtained at a temperature outside the permitted range are displayed together with a thermometer symbol (🌡). Please refer to Chapter 9 “Display messages and troubleshooting” for a complete list of display messages and symbols.

5.2 Viewing test results

▶ With the meter turned off, press the MEMO button. The meter turns on without advancing a test strip from the drum. The most recent test result and “MEMO” are displayed.



ⓘ **Only** turn on the meter with the MEMO button when you would like to review results held in memory.
If you turn on the meter with the ON/OFF button and there is a drum in the meter, a test strip will be advanced.

▶ Press the SET button to move towards the “oldest” result stored.

▶ Press the MEMO button to scroll forward to the “most recent” result again.

You can hold down the buttons to scroll through your results more quickly.

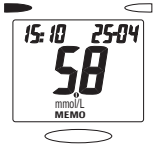
▶ Press the ON/OFF button to turn the meter off.
A test strip is not ejected.

ⓘ If you did not set the time and date, your results will be displayed with the number of their memory location.

5.3 Highest value, lowest value, average

Your meter can display the highest and lowest blood glucose results and the average (or mean) of current test results. Statistics are based on the test results stored for the last 7 days, as long as they were saved with the date and time. If more than 100 tests were carried out during this period, statistics will be based on the last 100.

- Press the MEMO button to enter memory.
  The meter turns on without advancing a test strip from the drum. The most recent test result and "MEMO" are displayed.

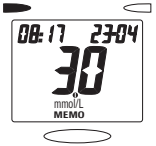


- Press the SET and MEMO buttons at the same time.
  The average of your current test results is displayed, identified by an "A".

When the average is being calculated, all results flagged as control readings are ignored.

- Press the MEMO button again.
  The highest measured test result is displayed together with the time and date.

- Press the MEMO button again.
  The lowest measured test result is displayed together with the time and date.



- Press the ON/OFF button to turn the meter off.
  A test strip is not ejected.

5.4 Downloading data to a PC or handheld computer

Your Accu-Chek Integra meter has an inbuilt infrared interface permitting cordless data downloading to a suitably equipped PC or handheld computer. All results in memory are downloaded each time.

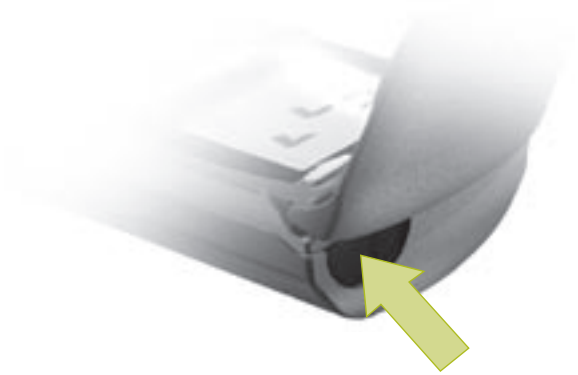
For data downloading you need a suitable PC program as well as the Accu-Chek Infrared Cable.
Roche Diagnostics offers a variety of special software programs (e.g. Accu-Chek Compass, Accu-Chek Pocket Compass and Accu-Chek Camit Pro) to expand the memory functions in your Accu-Chek Integra meter. Such programs enable you and your doctor to manage your data more effectively and, through graph and table views, make it easier for you to understand your self-testing data.

Not all software programs are available in all countries. For further information please contact your local customer support and service centre.

Data can only be evaluated on a PC or handheld computer as long as you have set the time and date (see Chapter 3.4 “Setting the time” and Chapter 3.5 “Setting the date”).

Your results remain in the meter’s memory following downloading to a PC or handheld computer.

- Install the software according to the manufacturer’s instructions.
- Locate the infrared window on the Accu-Chek Integra meter.
- Position the infrared cable less than 10 cm away, so the two infrared windows are pointing toward one another.



▶ Press the SET button and MEMO button at the same time.
The meter turns on without advancing a test strip from the drum. Two arrows appear in the display.

The meter automatically downloads all stored blood glucose test results to your computer. The two arrows flash in the display during the download.

Once downloading has finished, the meter turns off automatically. A message is displayed on the computer indicating that the data transfer is complete. The computer turns the Accu-Chek Integra meter off.

If data transfer did not occur or was incomplete, the two arrows do not start to flash and the meter turns off automatically after 5 minutes. Please refer to Chapter 9 “Display messages and troubleshooting”.

6 Checking the Accu-Chek Integra meter

6.1 Quality control checking with Accu-Chek Integra control solution

To ensure your results are always dependable, you must periodically check the performance of your Accu-Chek Integra meter.

Do this by running a quality control check using Accu-Chek Integra Control solution (not supplied with the meter):

- when you open a new pack of test strip drums
- after you have replaced the batteries
- if your meter flashes “CTRL”, indicating that a quality control test is required
- after you have cleaned your meter
- if your result does not agree with how you feel

Please contact your local customer support and service centre for details of where you can obtain Accu-Chek Integra Control solution (see Chapter 19 for details).

6.2 Performing a quality control check

- Read the package insert that came with the control solutions.
- Open the display cover.
- Press the ON/OFF button. The meter turns on.
- Check during the standard display test that all the segments making up the numerals are properly displayed.

If a segment is missing, test results may be displayed inaccurately (e.g. through a "8" being confused with a "3"). If this happens, call your local customer support and service centre.

- Wait until the flashing hand symbol and blood drop symbol appear in the display and the meter beeps (provided the beep tone is turned on).
- Press the SET button. "CTRL" appears in the display.

If you press the SET button before the hand symbol and the drop of blood appear in the display, "CTRL" will appear together with these in the display.

If you pressed the SET button inadvertently, you can press it again in order to remove the control test flag.

If "CTRL" flashes in the display because the meter asked you to run a quality control check (e.g. because you inserted a partially used test strip drum) and you press the SET button, "CTRL" stops flashing.

You now have approximately 5 minutes in which to apply control solution. After this time the meter automatically turns off. This strip can no longer be used. If this occurs, press the ON/OFF button to eject the test strip. Start the quality control check again with a new test strip.

- Take one bottle of control solution.
- Open it and wipe the tip of the dropper with a clean paper towel in order to remove dried-on residues.
- Point the dropper downwards at an angle.
- Gently squeeze the bottle until a small drop of solution is suspended from the tip.
- Touch the drop against the black notch at the front edge of the test strip.

6.2 Performing a quality control check

The control solution you apply to the test strip must come from a suspended drop. Do not apply control solution that has trickled down the outside of the dropper, as this will possibly generate results that are too high.

As soon as a sufficient amount of control solution has been drawn up, the meter beeps and the test commences automatically. 000 appears in the display at the start of the test and gradually disappears while the test is running.

Always hold the meter so the test strip is pointing downwards when you are applying control solution. If you hold it with the test strip pointing upwards, control solution can enter the meter and contaminate it.

On completion of the test, the result appears in the display together with the flashing test strip symbol and "CTRL". The meter saved the result simultaneously together with "CTRL".

▶ Refer to the table of expected values on the peel-off label of the test strip drum container.

If the result is outside this range, run another quality control check. If the result of the second test is outside the expected range as well, please check the following points:

- Did you perform the quality control check as directed?
- Did you perform the test within the correct temperature range (+10 °C to +40 °C)?
- Did you use a test strip drum whose 90-day "use-by" period has not expired (see Chapter 2.5 "Inserting or replacing the test strip drum")?
- Did you observe the proper storage conditions for the meter, test strip drum and control solution (see Chapter 8 "Measurement and storage conditions" and the package inserts that came with the test strip drum and control solution)?
- Did you use a control solution that is not beyond its expiry date (see label on bottle)?
- Has the control solution been open for more than three months? Once opened, control solutions are stable for three months. They must not be used after this period.
- Did you use the correct quality control solution (Accu-Chek Integra Control)?

6.2 Performing a quality control check

If you are unable to identify or eliminate the source of the problem please contact Customer Support (see Chapter 19 for details).

- Hold the meter upright and press the ON/OFF button.
  The used test strip falls out at the bottom.

Control readings (identified by “CTRL”) are not used in statistical calculations.

7 Cleaning the Accu-Chek Integra meter

The Accu-Chek Integra meter utilizes an optical measuring method that relies heavily on all of its components being clean. Owing to the way the test strip works, the meter does not normally come into direct contact with blood or control solution. Regular cleaning is therefore largely unnecessary. In the rare event of it becoming soiled through improper use, cleaning may become necessary (see error message “OFF” on page 92).

For cleaning use only cold water. Any other cleaning agents may damage the meter or impair its measuring function. Use a lightly moistened cloth or a lightly moistened cotton swab. Do not spray anything onto the meter and do not immerse it in water. This may damage internal parts, so affecting its operation.

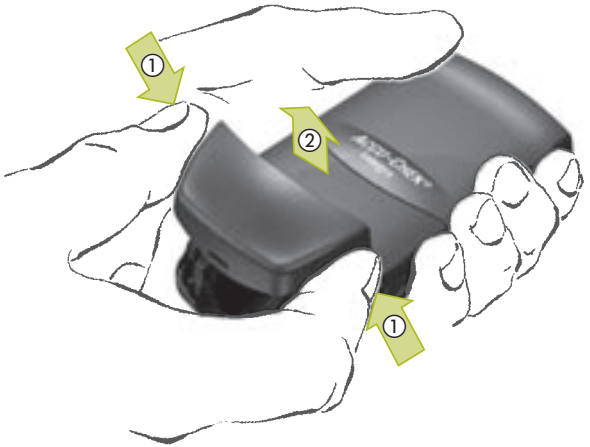
If the outside of your meter or the display are dirty, wipe them with a lightly moistened cloth.

7 Cleaning the Accu-Chek Integra meter

Clean the meter carefully, if

- the test strip guide has become visibly soiled,
- the message OFF is displayed (see page 92).

▶ Remove the cover from the measurement optics by slightly squeezing it from both sides (1) and lifting it off (2).



▶ Clean the small window covering the optical system, its surroundings and the test strip guide carefully with a lightly moistened cotton swab or a soft, lint-free cloth.

Make sure that no liquid enters the meter itself and avoid scratching the measurement optics, as this will impair the measuring function.

- ▶ When all of the components are thoroughly dry, check that the meter is clean (no lint or fluff remaining).
- ▶ Place the optics cover back in position from above. Press on the left and right sides of the cover. The cover quietly clicks back into place.
- ▶ Perform a quality control check (see Chapter 6, “Checking the Accu-Chek Integra meter”).

Please ensure that the optical system cover is firmly in place before you test. Otherwise it may block the strip from moving into test position or from being ejected.

If you use 70 % alcohol or a strongly diluted rinsing solution, wipe these fluids off immediately after application. Do not use cleaning agents that contain acetic acid (vinegar) or scouring agents because they can damage the display and the measurement optics.

8 Measurement and storage conditions

When testing blood glucose, pay close attention to the following points. They affect the dependability of your Accu-Chek Integra meter and the accuracy of your results.

8.1 Temperature range

- Without batteries and test strip drum, the meter may be stored at between -40 °C and +70 °C.
- With batteries but without the test strip drum, the meter may be stored at between -10 °C and +50 °C.

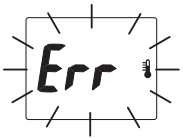
  At temperatures above +50 °C the batteries could leak and damage the meter.

  At temperatures below -10 °C the batteries do not have enough power to keep the internal clock functioning.

- With batteries and test strip drum, the meter may be stored at between +2 °C and +30 °C.
- For performing blood glucose tests the permitted range is from +10 °C to +40 °C.

8.1 Temperature range

- A test can be performed at the limits of the permitted range (between +5 °C and +10 °C or between +40 °C and +45 °C), but the result should be interpreted with caution and should not be used as a basis for making therapeutic decisions. A thermometer symbol (🌡) flashes in the display.
- Tests cannot be performed at temperatures outside the permitted range (below +5 °C or above +45 °C). The following message is displayed:



Do not use results obtained at the limits of the permitted temperature range as a basis for making therapeutic decisions. Your blood glucose test results may be incorrect. Incorrect results can cause the wrong therapeutic decision to be taken and so produce adverse health effects.

Never try to speed up warming or cooling of your Accu-Chek Integra meter artificially (e.g. by placing it on a radiator or in a refrigerator). Doing so can damage your meter and cause it to give incorrect results. Incorrect results can cause the wrong therapeutic decision to be taken and so produce adverse health effects.

8.2 Atmospheric humidity

Keep the meter at below 85 % relative humidity.

Sudden changes in temperature cause condensation to form on or within the meter. If this happens, do not turn the meter on. Wait until it is thoroughly dry again. Make sure that it returns to room temperature slowly. Never keep it in a room that is likely to harbour condensation (e.g. a bathroom).

8.3 Sources of interferences

Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use this meter close to sources of strong electromagnetic radiation.

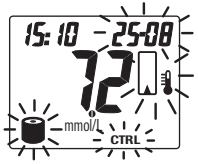
To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

9 Display messages and troubleshooting

When you use your Accu-Chek Integra meter, various letters and symbols will appear on the display and also at times error messages. Some of the routine display messages have already been explained. Following is a complete list of display messages, what they mean, and what action you should take in case you see an error message.

Please watch out for any messages displayed when you use the meter. Every message provides you with important information. Therefore, if you do not recognize a symbol or do not understand a message, please refer immediately to this chapter for an explanation. Otherwise you run the risk of misinterpreting your blood glucose results.

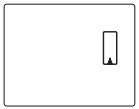
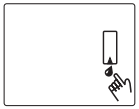
Please note:
Several messages may be displayed simultaneously. For example, in this display the blood glucose result and time are not flashing while date, test strip symbol, thermometer symbol, drum symbol and "CTRL" are flashing.



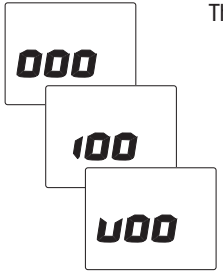
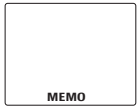
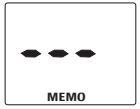
This means that the temperature during testing was at the limits of the permitted range, the 90-day use-by period for the test strip drum has expired and the test strip is still in the meter.

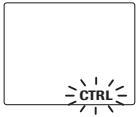
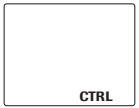
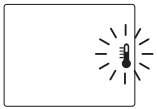
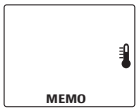
9.1 Messages and symbols

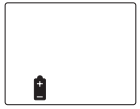
When symbols and numbers are surrounded by a halo, it indicates that they are flashing in the meter's display.

This message/ symbol appears ...	and means:
	This is a pre-programmed unit displayed with the blood glucose result. (See Chapter 2.2)
	The beep tone is turned on.
	A test strip is being advanced or is still in the meter.
	You may apply blood or control solution to the test strip now.

9.1 Messages and symbols

This message/ symbol appears ...	and means:
	The test is in progress.
	**MEMO** indicates a value saved in memory.
	• No results have been saved. • The meter cannot calculate the average value ▪ as memory only contains results that are not considered in the calculation, e.g. quality control results, ▪ as you have not entered the time and date, ▪ as you have set the date to a time in the past.

This message/ symbol appears ...	and means:
	You are requested to run a quality control test.
	This is/was a quality control test.
	The temperature during testing is at the limits of the permitted range (between +5 °C and +10 °C or between +40 °C and +45 °C). Do not use the result as a basis for therapeutic decisions. Turn the meter off. Let the meter slowly cool down or warm up. Turn the meter on and repeat the test. The optimum measuring temperature is between +10 °C and +40 °C.
	The result in memory was obtained outside the permitted temperature range. Do not use the result as a basis for therapeutic decisions.

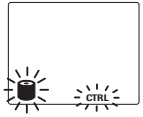
This message/ symbol appears ...	and means:
	The battery is running low. When this symbol first appears, you can perform approximately a further 50 tests. Continue testing until all the test strips in the test strip drum have been used. Then insert two new batteries (type AAA) and a new test strip drum. When the batteries are so weak that no more tests can be performed, the battery symbol appears briefly for 3 seconds in the display. Then the meter turns off. Insert two new batteries (type AAA).
	The blood glucose result is below the measuring range (<0.6 mmol/L or 10 mg/dL). If this test result agrees with the way you feel, follow your doctor's advice. If the way you feel does not agree with this test result, please perform a quality control check with the Accu-Chek Integra Control solution and a new test strip. Repeat the blood glucose test. If you feel the new result is also implausible, please contact your doctor.

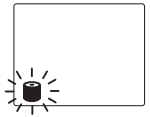
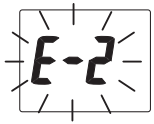
This message/ symbol appears ...	and means:
	The blood glucose result is above the measuring range (>33.3 mmol/L or 600 mg/dL). If this test result agrees with the way you feel, follow your doctor's advice. If the way you feel does not agree with this test result, please perform a quality control check with the Accu-Chek Integra Control solution and a new test strip. Repeat the blood glucose test. If you feel the new result is also implausible, please contact your doctor.

9.2 Troubleshooting

When symbols and numbers are surrounded by a halo, it indicates that they are flashing in the meter's display.

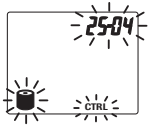
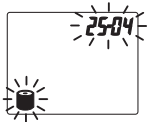
If this happens ...	it means:
Meter will not turn on.	• Batteries are empty. Insert new batteries. • Ambient temperature is too low. Move somewhere warmer. Let the meter slowly warm up. • Meter is defective. Contact Customer Support (see Chapter 19 for details).
The meter is turned on, but the display remains blank.	The display is defective. Contact Customer Support (see Chapter 19 for details).
Clock has stopped or clock is slow after the meter is turned on.	The meter was exposed to temperatures below -10 °C and the batteries are starting to freeze. Turn the meter off. Let the meter slowly warm up. With batteries always store the meter at between -10 °C and +50 °C (with test strip drum at between +2 °C and +30 °C).

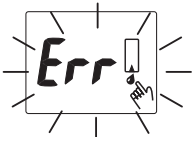
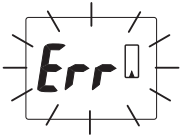
This message/ symbol appears ...	and means:
	The test strip drum in the meter is empty. Insert a new drum. If the message is still displayed, please contact Customer Support (see Chapter 19 for details).
	• You inserted a test strip drum that has already been used. • You opened the drum compartment. • You changed the batteries without changing the test strip drum at the same time. You are requested to run a quality control check. The meter cannot determine how long the test strip drum has been outside the meter, or whether it is still usable. If you are certain that the 90-day "use-by" period has not been exceeded, you may continue to use the drum. Perform a quality control check. The result of the quality control check will be stored in memory along with the flashing drum symbol and "CTRL". The drum symbol will remain displayed until a new drum is inserted. All test results will be stored along with the flashing drum symbol. If you do not perform a quality control check, the flashing drum symbol and the flashing "CTRL" will appear with every new test until a new drum is inserted.

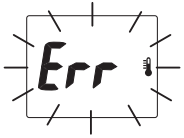
This message/ symbol appears ...	and means:
	• You inserted a test strip drum that has already been used. • You opened the drum compartment. • You changed the batteries without changing the test strip drum at the same time. You performed the requested quality control check and flagged it as such.
	The bar code information from the test strip drum has been lost. Turn the meter off. Open the drum compartment and close it again. The meter then rotates the drum and reads the bar code. The drum symbol and “CTRL” then flash in the display. Perform a quality control check. You can use all remaining test strips. The 90-day use-by period will no longer be properly calculated for this drum. The drum symbol continues to flash in the display until a new drum is inserted.

This message/ symbol appears ...	and means:
	• There is no test strip drum in the meter. Turn the meter off. Insert a test strip drum. • You inserted a test strip drum from a different blood glucose monitoring system. Turn the meter off. Insert an Accu-Chek Integra test strip drum. • The bar code on the drum is damaged. Turn the meter off. ▪ If you inserted the first drum from a pack, remove the drum from the meter and return it to its container. Insert the second drum from the package and use all 17 test strips. When it is time to replace the drum, insert the first drum with the damaged bar code. When the error message is displayed, press the SET button. The meter uses the code from the previous drum. The drum symbol and “CTRL” flash in the display, requesting you to perform a quality control check. You can use all 17 test strips. The drum symbol continues to flash in the display until a new drum is inserted.

This message/ symbol appears ...	and means:
	■ If you inserted the second or third drum from a pack, press the SET button. The meter uses the bar code from the first drum. The error message “E-2” disappears. The drum symbol and “CTRL” flash in the display, requesting you to perform a quality control check. You can use all 17 test strips. The drum symbol continues to flash in the display until a new drum is inserted. ■ If you inserted a drum from a single-drum pack, you can no longer use this drum. Insert a new drum. ⚠ All test strip drums in the same package have a bar code unique to that package. Do not try to code the meter using drums from a different package. If the test strips and bar code do not belong together, inaccurate blood glucose results may be obtained. Check you are using the correct drums by comparing their lot codes. The lot code is printed on the label of the test strip drum next to the LOT symbol.

This message/ symbol appears ...	and means:
	If the message is still displayed, please contact Customer Support (for details see Chapter 19).
	The 90-day “use-by” period has been exceeded. The test strips in the drum are unusable. Insert a new drum. ⚠ If you continue to use the drum, carry out a quality control check. The test results obtained under these conditions may only be used for reference purposes and must not be used for decisions regarding therapy. Date and drum symbol continue to flash in the display until a new drum is inserted.
	• The 90-day “use-by” period has been exceeded. You performed the requested quality control check and flagged it as such. • When retrieving results: The test strips used to obtain the stored result were unusable (more than 90 days old). ⚠ The test results obtained under these conditions may only be used for reference purposes and must not be used for decisions regarding therapy.

This message/ symbol appears ...	and means:
	A test error has occurred. Turn the meter off and on again. Repeat the test.
	There was not enough blood or control solution on the test strip. Turn the meter off and on again. Repeat the test with a larger drop of blood or control solution and a new test strip.
	• You forcibly removed the test strip during testing. Turn the meter off and on again. Repeat the test with a new strip, this time ejecting it by means of the ON/OFF button. • You bent the test strip while applying blood or control solution or during measurement. Turn the meter off and on again. Repeat the test with a new strip. • The optical system cover may not be closed properly. Ensure that the optical system cover is firmly in place.

This message/ symbol appears ...	and means:
	The test strip is stuck in the guide. Turn the meter off. Pull the strip out of the meter. Open the drum compartment and remove the drum. Reinsert the drum and close the drum compartment. The drum symbol and “CTRL” flash in the display when the meter is turned on. Perform a quality control check. You can use all remaining test strips. The 90-day use-by period will no longer be properly calculated for this drum. The drum symbol continues to flash in the display until a new drum is inserted.
	It is too warm or too cold for the test, i.e. warmer than +45 °C or colder than +5 °C. No test result is displayed or saved. Turn the meter off. Let the meter and test strips slowly cool down or warm up. Turn the meter on and repeat the test. The optimum measuring temperature is between +10 °C and +40 °C.

This message/ symbol appears ...	and means:
	• You applied the blood drop or control solution drop too soon. Turn the meter off and on again. Repeat the test. Wait until the flashing hand symbol and blood drop symbol appear in the display and the meter beeps (provided the beep tone is turned on) before applying blood or control solution. • The optical system is dirty. Clean the optical system (see Chapter 7 “Cleaning the Accu-Chek Integra meter”) and repeat the test. • The meter was turned off and on again. The strip is still in the meter. Turn the meter off. Hold the meter upright and let the strip drop out, or remove the strip manually, even if it takes a small amount of force. • You forcibly removed the test strip during testing. Turn the meter off and on again. Repeat the test with a new strip, this time ejecting it by means of the ON/OFF button.

This message/ symbol appears ...	and means:
	• The test strip that has been advanced is defective. Hold the meter with the strip pointing downwards. Turn the meter off and let the strip drop out. Turn the meter on again. Repeat the test with a new test strip.
	The two arrows do not start to flash. The meter turns off after 5 minutes and the computer displays a download-related error message. • An error occurred while data was being downloaded. Download the data again. • A bright light source is too close to one of the infrared windows. Increase the distance to the light source and re-start the data download.

This message/ symbol appears ...	and means:
	• The meter and the infrared cable are too far away from one another or not correctly aligned. Decrease the distance between the infrared windows of the two devices to less than 10 cm. Make sure the two infrared windows are pointing towards one another. Re-start the data download. • A computer software error occurred. Read the Manual for the download software.
	• Electrostatic discharge Turn the meter off and on again. • Meter is defective. Please contact Customer Support (see Chapter 19 for details).

10 Technical data

Meter type	Accu-Chek Integra
Catalogue number/serial number	See type plate on the back of the meter.
Test principle	Determination of glucose in fresh capillary blood by reflectance photometry. When using different specimen material please refer to the package insert that came with the Accu-Chek Integra test strip drums.
Measuring range	0.6–33.3 mmol/L (10–600 mg/dL)
Sample size	Approx. 1.5 µL (1 microlitre = 1 thousandth of a millilitre)
Measuring time	Approx. 15 seconds (depending on concentration)
System operating conditions	+10 °C to +40 °C
Meter storage conditions	Without batteries and test strip drum: -40 °C to +70 °C With batteries but without test strip drum: -10 °C to +50 °C With batteries and test strip drum: +2 °C to +30 °C

Humidity	Less than 85 % relative humidity
Memory capacity	100 test results with time and date, average, highest and lowest blood glucose reading
Dimensions	103 x 52 x 31 mm
Weight	Approx. 120 g with batteries and test strip drum
Display	Liquid Crystal Display (LCD) with symbols
Automatic power-off	After 60 seconds / 5 minutes depending on testing status
Power supply	2 batteries (type AAA, LR 03, AM 4 or Micro)
Battery life	at least 500 readings
Interface	Infrared interface
Safety class	III
LED/IRED	Laser Class 1

Electromagnetic compatibility This device meets the electromagnetic immunity requirements as per ISO 15197 Annex A. The chosen basis for the immunity tests was basic standard IEC 61000-4-2. In addition it meets the electromagnetic emissions requirements as per EN 61326. Its electromagnetic emission is thus low. Interference from other electrically driven equipment is not to be anticipated.

Blood glucose concentrations may be measured in whole blood or plasma. Although you always apply whole blood to the test strip, your meter displays blood glucose results that relate either to whole blood or plasma. To see whether your blood glucose meter displays results relating to whole blood or to plasma, see the package insert that came with your test strips. It also contains information on how the system works, on the test principle and on reference methods.

Part 2

ACCU-CHEK® Softclix

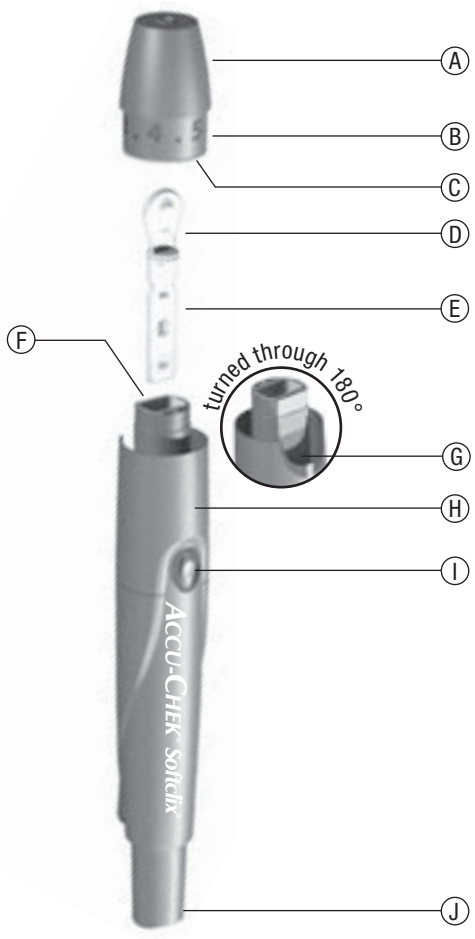
Lancing Device

Instructions for Use

11 Introduction

11.1 Your lancing device at a glance

A	Cap
B	Comfort Dial (for depth selection)
C	Notch
D	Protective cap
E	Lancet
F	Lancet holder
G	Semi-circular cut-out
H	Ejector
I	Transparent release button
J	Priming button



11.2 About the Accu-Chek Softclix lancing device

The Accu-Chek Softclix lancing device is an easy-to-use lancing device that has been specially developed to allow virtually pain-free collection of capillary blood from a fingertip or earlobe.

The depth of lancet penetration can be precisely adjusted to suit individual skin requirements.

Use the Accu-Chek Softclix lancing device only with Accu-Chek Softclix lancets, as using any other lancet may prevent or impair the proper functioning of the lancing device.

The Accu-Chek Softclix lancing device is intended for self-monitoring by a single person. It must not be used on more than one person due to the risk of infection.

12 Using the Accu-Chek Softclix lancing device

12.1 Inserting or exchanging the lancet

Pull off the cap.

If there is already a lancet in the lancing device, slide the ejector forwards to remove it.

Insert a new lancet in the lancet holder. and push it until it clicks.

Remove the protective cap from the lancet with a twisting motion.

12.1 Inserting or exchanging the lancet

Press the cap on again until it clicks. Be sure to align the notch on the cap with the centre of the semi-circular cut-out on the ejector.

⚠ To avoid infection, use a new lancet each time you take blood.

Using each lancet once only helps ensure virtually pain-free blood sampling.

⚠ Carefully dispose of used lancets so they cannot cause injury.

12.2 Preparations for taking blood

The best place for obtaining capillary blood is from a fingertip or an earlobe. We recommend using the side of a fingertip, as this registers least pain.

Wash hands with warm water and soap and dry well. This helps ensure proper hygiene and stimulates blood flow.

Selecting penetration depth with the Comfort Dial

Modern blood glucose meters can take readings using just a tiny drop of blood. Usually, enough blood can be obtained with a low depth setting.

This significantly reduces the pain of pricking the skin, after-pain is reduced or absent altogether, and tissue scarring is minimized.

The penetration depth is set by rotating the Comfort Dial (cap).
If you are using the Accu-Chek Softclix lancing device for the first time, set the depth selection dial to 1.

12.3 Obtaining blood

First check that you have set the desired penetration depth.
Press in the priming button until it clicks. Be careful not to press the release button at the same time. The lancing device is primed when a yellow dot appears in the transparent release button.

Gently press the lancing device against the fingertip or earlobe and press the release button, taking care not to push against the priming button or to impede its free movement.

Gently massage the fingertip or earlobe to encourage a drop of blood to form. If you do not obtain sufficient blood, try again with progressively deeper settings.

Perform a blood glucose test as described in Chapter 4 “Testing blood glucose”.

Do not prime the Accu-Chek Softclix lancing device until you are ready to take blood.

Never expose the Accu-Chek Softclix lancing device to extreme temperatures (e.g. in a hot car).

Subsequent treatment of the puncture site
Wipe the puncture site with a dry, clean paper towel and keep it clean.

12.4 Cleaning the Accu-Chek Softclix lancing device

Clean the Accu-Chek Softclix lancing device weekly using a cloth moistened with water or 70 % alcohol (available from your pharmacist).

In addition, thoroughly wipe the inside of the cap using a cotton bud moistened with 70 % alcohol.

Allow the Accu-Chek Softclix lancing device time to dry thoroughly.

Never dip the Accu-Chek Softclix lancing device in water or alcohol.

Part 3

ACCU-CHEK®
Softclix AST

ACCESSORY

Clear plastic AST cap for blood glucose determination with Accu-Chek Integra on alternative sites

Instructions for Use

13 Introduction

13.1 A new way to test

Traditionally, blood samples for blood glucose testing are taken from the fingertip or from the earlobe. With the Accu-Chek Integra system, you now also have the option of using capillary blood samples from other sites, such as the base of the thumb, the forearm, the upper arm or the calf. Testing with blood from these alternative sites is referred to as Alternative Site Testing (AST).

Blood from the fingertip can be used for testing at any time. If alternative sites are used, there are certain times which are not suitable for testing. Before you take a sample from a site other than the fingertip you should therefore read these instructions so that you can decide which option is right for you. Please consult your physician before using alternative sites for blood glucose testing.

Use the AST cap exclusively for collecting blood from alternative sites.
If you use this cap to collect blood from a fingertip, the lancet penetrates too deep into the finger. Pricking the skin is then very painful and can result in injury.

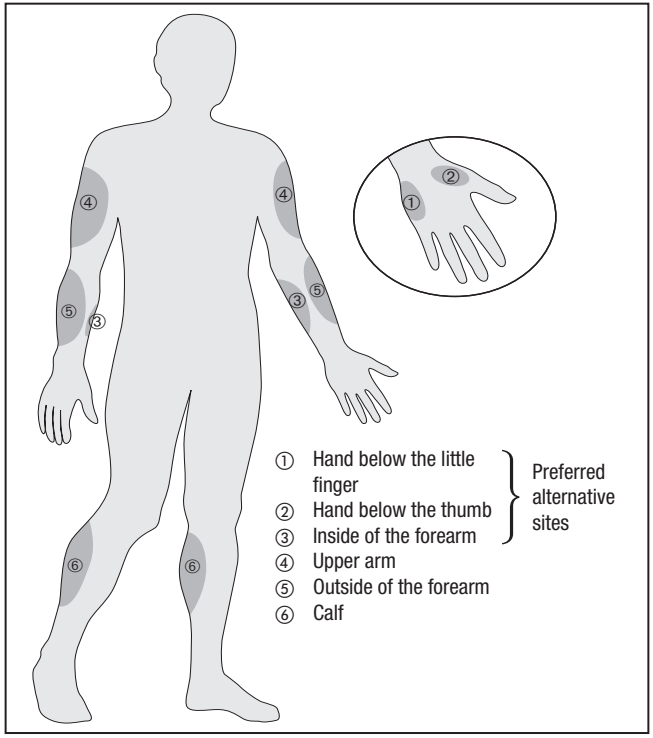
Please also follow the instructions for your Accu-Chek Integra blood glucose meter and test strips and for the Accu-Chek Softclix lancing device.

The Accu-Chek Softclix lancing device and Accu-Chek Softclix AST Accessory are intended for self-monitoring by a single person. They must not be used by more than one person due to the risk of infection.

To avoid infection, use a new lancet each time you take blood. Using each lancet once only helps ensure virtually pain-free blood sampling.

In rare cases bruising may occur after sampling.

Alternative Sites for Testing


① Hand below the little finger
② Hand below the thumb
③ Inside of the forearm
④ Upper arm
⑤ Outside of the forearm
⑥ Calf
Preferred alternative sites

13.2 Important information for users

Before you perform a test with blood from an alternative site, you should be aware of the following limitations:
Capillary blood from the fingertip responds more quickly to changes in blood glucose levels than blood from alternative sites. Blood glucose values measured in blood taken from these sites may therefore differ from values measured in blood from the fingertip. This is because the fingertips contain more blood vessels than other sites.

Because of the possibility of discrepant blood glucose readings, alternative site testing is **not** recommended:

- up to two hours following a meal when blood glucose values are rising quickly
- after exercise
- if you have a temperature or if a medical condition is limiting your mobility, e.g. after breaking a leg or being confined to bed
- if you suspect that your blood glucose is extremely low (hypoglycaemia)
- if you know that you sometimes do not notice when you are hypoglycaemic
- during peak action time of basal insulin or fast-acting insulin analogues
- up to two hours after injecting a fast-acting insulin analogue

13.2 Important information for users

If you are considering AST for your glucose measurements, please discuss this first with your healthcare professional.

If the displayed blood glucose result does not match how you feel, you should do a fingertip test to check the result. If the fingertip result still does not match how you feel, contact your doctor.

Do not change your treatment decisions based on just one AST result.

The success of collecting a suitably sized drop of blood from alternative sites may differ from person to person and from alternative site to alternative site.

Pre-test Checklist

14 AST testing

14.1 Preparing for AST testing

1. Remove the blue cap from the Accu-Chek Softclix lancing device.

2. Insert a new Accu-Chek Softclix lancet into the lancet holder and push it in until it clicks. Remove the protective cap from the lancet with a twisting motion.

3. Now place the clear plastic AST cap on the device and press until it clicks. Set the penetration depth to the highest setting (5.5). (For AST on the base of the thumb a setting of 3-4 is often sufficient.)

   To obtain a sufficiently large drop of blood from alternative sites, lancing must be deeper than on the finger. However, these sites are usually less sensitive to pain and most patients don`t feel any pain at all.

   Do not use the clear cap for sampling from the fingertip!

4. Press in the priming button until it clicks (the lancing device is primed when a yellow dot appears in the transparent release button).

5. Choose a fleshy area of the alternative site and wash it with warm, soapy water or use an alcohol wipe. Ensure that the skin is dry before taking a blood sample.

As an example you can use the top side of your forearm, approximately 5 cm below the elbow.

6. Firmly press the clear AST cap against the selected site. Press the release button and continue to apply pressure to the site for a couple of seconds. You can watch the drop of blood form through the clear cap.

The blood drop should be approximately this size: ●

If the drop is smaller, release the pressure for a few seconds, keeping the device on the skin. Then re-apply pressure until you get a sufficiently large drop of blood.

14.2 Measuring blood glucose

1. Obtain a drop of blood as described above.

2. Hold the meter so the test strip is pointing downwards at a slight angle. Touch the front edge of the test strip against the blood without delay.

   The strip draws up the blood. As soon as the correct amount of blood has been drawn up, the meter beeps and the test commences automatically. The meter recognizes if too little blood has been applied and displays an error message. 000 appears in the display at the start of the test.

3. Dispose of the used lancets and test strips safely.

4. Remove the clear AST cap from the lancing device and replace it with the original plastic cap.

15 Cleaning the Accu-Chek Softclix lancing device and the AST Cap

Clean the lancing device weekly using a cloth moistened with soapy water or 70 % alcohol (available in pharmacies).
In addition, thoroughly wipe the inside of the blue cap and the clear AST cap using a cotton bud moistened with 70 % alcohol.
Allow the lancing device and the two caps to dry thoroughly before performing a new test.

Notes:

- Do not prime the device until you are ready to take blood.
- Carefully dispose of used lancets to avoid injuries.
- Never expose the Accu-Chek Softclix lancing device to extreme temperatures (e.g. in a hot car).
- Never dip the Accu-Chek Softclix lancing device in water or alcohol.

Part 4

ACCU-CHEK® Integra

BLOOD GLUCOSE MONITORING SYSTEM

Appendix

16 System components

With your Accu-Chek Integra meter use only Accu-Chek Integra test strip drums. The drums contain 17 test strips. Each drum comes individually packaged in its own container.
The test strip drums are available from your pharmacist or Diabetes Australia.

For quality control checking of your Accu-Chek Integra meter use only Accu-Chek Integra Control solutions (see Chapter 6 “Checking the Accu-Chek Integra meter”).

For virtually pain-free blood sampling we recommend the Accu-Chek Softclix lancing device and Accu-Chek Softclix lancets. These are available in various pack sizes:

- 25 Accu-Chek Softclix lancets REF 0 3307492001
- 100 Accu-Chek Softclix lancets REF 0 3307506001
- 200 Accu-Chek Softclix lancets REF 0 3307484001

N.B. Not all pack sizes may be available in all countries.

- To order a new AST cap please contact your nearest Roche Diagnostics office.

17 Guarantee

The statutory guarantee provisions governing the sale of consumer goods in the country of purchase shall prevail.

18 Patents

Accu-Chek Integra blood glucose meter

Patents:
US 5,463,467, US 5,720,924, US 5,863,800, US 6,707,554, US 6,475,436
Patent Applications:
EP 0 622 119, EP 0 632 262, EP 1 022 565, EP 1 117 989, EP 1 189 064, US patents pending

Accu-Chek Softclix lancing device

EP-B-0565970, EP 1 034 740, US Re 35803, US 4,924,879, US 6,419,661
German Design Model: DE 49900488.4

Your purchase entitles you to use the Accu-Chek Softclix lancing device exclusively with Accu-Chek Softclix lancets.

19 Local customer support and service

19.1 Information and repair

Information service
If you have any questions on how to use your Accu-Chek Integra meter or Accu-Chek Softclix lancing device or the AST cap, if any of the results you obtain seem implausible, or if you suspect the meter or lancing device have a fault, please contact customer support and service. See the next chapter for details.

Repair service
Please note that any repair, adjustment or other change of the meter or lancing device must only be performed properly by persons who have been authorized by Roche Diagnostics. If you suspect that the meter or lancing device have a fault, please start by contacting your Roche Diagnostics customer support representative. Our staff will attempt to identify and solve your problem over the phone.

19.2 Contact us

Accu-Chek Enquiry Line: Freecall 1800 251 816

Roche Diagnostics Australia Pty Ltd.
31 Victoria Avenue
Castle Hill, NSW 2154

Telephone: (02) 9899 7999
Facsimile: (02) 9894 7831

Web: www.accu-chek.com

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